Reprinted
February 5, 2002

SENATE BILL No. 228

DIGEST OF SB 228 (Updated February 4, 2002 4:18 PM - DI 104)

Citations Affected: IC 12-7; IC 12-15; IC 12-17.6; IC 25-1; noncode.

Synopsis: Prior authorization of drugs under Medicaid and CHIP. Prohibits the use of prior authorization for antianxiety, antidepressant, and antipsychotic drugs under Medicaid and the children's health insurance program (CHIP). Provides that this prohibition does not apply to a formulary or prior authorization program operated by a managed care organization under the Medicaid or CHIP programs. Establishes procedures to follow for requiring prior authorization for other drugs under the Medicaid and CHIP programs. Allows the office of Medicaid policy and planning to place limits on quantities dispensed or the frequency of refills for any covered drug for the purpose of preventing fraud, abuse, waste, overutilization, or inappropriate utilization or to implement disease management. Establishes a therapeutics committee as a subcommittee of the drug utilization review (DUR) board and specifies committee membership and terms. Gives the DUR board the duty of developing and maintaining a preferred drug list for Medicaid's fee for service and primary care case management programs and CHIP in consultation with the therapeutics committee. Sets out implementation dates for the preferred drug list. Specifies that any drug that is included on the preferred drug list may not require prior authorization upon implementation of the preferred drug list. (The introduced version of this bill was prepared by the joint commission on Medicaid oversight.)

Effective: Upon passage; July 1, 2002.

Miller, Simpson

January 7, 2002, read first time and referred to Committee on Health and Provider Services.
January 29, 2002, amended, reported favorably — Do Pass.
February 4, 2002, read second time, amended, ordered engrossed.

Reprinted
February 5, 2002

Second Regular Session 112th General Assembly (2002)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2001 General Assembly.

SENATE BILL No. 228

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-7-2-51.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 51.8. "Cross-indicated drug", for purposes of IC 12-15-35.5, has the meaning set forth in IC 12-15-35.5-2.**

SECTION 2. IC 12-7-2-178.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 178.5. "Single source drug" ~~for purposes of IC 12-15-35-35, has the meaning set forth in IC 12-15-35-35(a).~~ **means an outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.**

SECTION 3. IC 12-7-2-190.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 190.6. "Therapeutic classification" or "therapeutic category", for purposes of IC 12-15-35, has the meaning set forth in IC 12-15-35-17.5.**

SECTION 4. IC 12-15-35-17.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 17.5. As used in this chapter, "therapeutic classification" or "therapeutic category" means a group of pharmacologic agents primarily characterized by a significant similarity of the biochemical or physiological mechanism by which these agents result in the intended clinical outcome.**

SECTION 5. IC 12-15-35-20.1, AS ADDED BY P.L.231-1999, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 20.1. (a) Each board member **and each therapeutics committee member** shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board **or committee** for recommendation or other action.

(b) A board member **or therapeutics committee member** may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member **or therapeutics committee member** who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

SECTION 6. IC 12-15-35-20.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 20.5. (a) The therapeutics committee is established as a subcommittee of the board.**

(b) The chairperson of the board elected under section 25 of this chapter shall, with the approval of a majority of a quorum of the board, appoint the members of the therapeutics committee.

(c) The therapeutics committee is composed of the following members:

(1) Seven (7) physicians licensed under IC 25-22.5, including:

(A) one (1) physician with expertise in the area of infectious diseases;

(B) one (1) physician with expertise in the area of pediatrics;

(C) one (1) physician with expertise in the area of geriatrics;

(D) one (1) physician with expertise in psychiatric medicine;

(E) one (1) physician with expertise in the area of internal

medicine and who specializes in the treatment of diabetes;

(F) one (1) physician with expertise in the area of cardiovascular medicine; and

(G) one (1) physician with expertise in the area of oncology or pain management.

(2) Six (6) pharmacists licensed under IC 25-26, including:

(A) one (1) pharmacist who has experience in pharmacy benefit management and is employed by a health maintenance organization that has a pharmacy benefit;

(B) one (1) pharmacist who is employed or has been employed by a hospital pharmacy;

(C) one (1) pharmacist who is employed or has been employed by a retail pharmacy;

(D) one (1) pharmacist who is employed or has been employed in the area of long term care pharmacy; and

(E) two (2) pharmacists who have a doctor of pharmacy degree or an equivalent degree and who have either:

(i) completed a residency in drug information; or

(ii) had at least three (3) years of recent experience in prescription drug formulary management, including therapeutic category review.

(d) Not more than three (3) of the individuals appointed by the chairperson under subsection (b) to the therapeutics committee may also be members of the board.

(e) At least three (3) of the members described in subsection (c)(1) and appointed under subsection (b) must have at least three (3) years of recent experience in prescription drug formulary management, including therapeutic category review.

(f) A member of the therapeutics committee may not:

(1) be employed by; or

(2) contract with;

a pharmaceutical manufacturer or labeler.

(g) The term of a member of the therapeutics committee is three (3) years. A member may be reappointed to the committee upon the completion of the member's term.

(h) The expenses of the therapeutics committee shall be paid by the office.

(i) Each member of the therapeutics committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection

with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(j) Each member of the therapeutics committee who is a state employee is entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and any other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(k) The affirmative votes of a majority of the voting members appointed to the therapeutics committee are required for the committee to take action on any measure.

(l) The therapeutics committee shall meet:

(1) upon the call of the chairperson of the therapeutics committee; and

(2) at least quarterly.

(m) The chairperson and the vice chairperson of the therapeutics committee:

(1) each serve for a term of one (1) year; and

(2) must be elected from the therapeutics committee's membership at the therapeutics committee's first meeting each calendar year.

(n) A meeting held by the therapeutics committee must be open to the public in accordance with IC 5-14-1.5.

SECTION 7. IC 12-15-35-26, AS AMENDED BY P.L.291-2001, SECTION 162, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 26. **(a)** The secretary shall provide additional staff to the board.

(b) The secretary shall provide staff for the therapeutics committee.

SECTION 8. IC 12-15-35-28 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 28. **(a)** The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the

provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to

ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The review of the committee's recommendations concerning a new prescription drug that has recently entered the market in order to determine whether the drug should be included on the preferred drug list.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give substantial consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program.

(d) A practitioner who is authorized to prescribe medication under IC 25 may prescribe a drug that is not on the preferred drug list if the practitioner receives prior authorization.

(e) The board, in consultation with the therapeutics committee,

shall approve or deny the inclusion on the preferred drug list of a single source drug that is newly approved by the federal Food and Drug Administration on the earlier of:

(1) thirty (30) days after the single source drug is approved by the federal Food and Drug Administration; or

(2) the date of the board's first scheduled meeting following the approval of the single source drug by the federal Food and Drug Administration.

SECTION 9. IC 12-15-35-28.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 28.5. The therapeutics committee established under section 20.5 of this chapter shall do the following:**

(1) Advise and make recommendations to the board in the board's development and maintenance of a preferred drug list under section 28 of this chapter.

(2) Submit to the board a proposed preferred drug list that has been approved by a majority of the voting members of the therapeutics committee.

(3) Advise and make recommendations to the board in the board's annual review and maintenance of a preferred drug list.

SECTION 10. IC 12-15-35-28.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 28.7. (a) The board shall submit the approved preferred drug list to the office not later than August 1, 2002.**

(b) The office may implement the preferred drug list developed and approved by the board under section 28 of this chapter after June 30, 2002. However, the office shall implement this list not later than September 1, 2002.

(c) The office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(d) The office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(e) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

SECTION 11. IC 12-15-35-35, AS AMENDED BY P.L.231-1999, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 35. ~~(a) As used in this section, "single source~~

~~drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.~~

~~(b)~~ **(a)** Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX

approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

~~(c)~~ **(b)** The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

~~(d)~~ **(c)** The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 12. IC 12-15-35-43 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 43. **(a)** Confidential data or information obtained by pharmacists as part of prospective DUR are confidential but may be released to prescribers or others according to procedures established by the board.

(b) The board, the therapeutics committee, or the office may not release proprietary information obtained as part of the development, implementation, or maintenance of a preferred drug list under this chapter.

SECTION 13. IC 12-15-35.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]:

Chapter 35.5. Prescription Drugs

Sec. 1. (a) Except as provided in subsection (b), this chapter applies to:

(1) the Medicaid program under this article; and

(2) the children's health insurance program under IC 12-17.6.

(b) This chapter does not apply to a formulary or prior authorization program operated by a managed care organization under a program described in subsection (a).

Sec. 2. As used in this chapter, "cross-indicated drug" means a drug that is used for a purpose generally held to be reasonable, appropriate, and within the community standards of practice even though the use is not included in the federal Food and Drug Administration's approved labeled indications for the drug.

Sec. 3. (a) Except as provided in subsection (b), the office may

establish prior authorization requirements for drugs covered under a program described in section 1(a) of this chapter.

(b) The office may not require prior authorization for the following single source or brand name multisource drugs:

(1) A drug that is classified as an antianxiety, antidepressant, or antipsychotic central nervous system drug in the most recent publication of Drug Facts and Comparisons (published by the Facts and Comparisons Division of J.B. Lippincott Company).

(2) A drug that, according to:

(A) the American Psychiatric Press Textbook of Psychopharmacy;

(B) Current Clinical Strategies for Psychiatry;

(C) Drug Facts and Comparisons; or

(D) a publication with a focus and content similar to the publications described in clauses (A) through (C);

is a cross-indicated drug for a central nervous system drug classification described in subdivision (1).

(3) A drug that is:

(A) classified in a central nervous system drug category or classification (according to Drug Facts and Comparisons) that is created after the effective date of this chapter; and

(B) prescribed for the treatment of a mental illness (as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

(c) Except as provided under section 7 of this chapter, a recipient enrolled in a program described in section 1(a) of this chapter shall have unrestricted access to a drug described in subsection (b).

Sec. 4. Prior authorization requirements developed under this chapter must:

(1) comply with all applicable state and federal law, including the provisions of 405 IAC 5-3 and 42 U.S.C. 1396r-8(d)(5); and

(2) provide that the prior authorization number assigned to an approved request be included on the prescription or drug order:

(A) issued by the prescribing physician; or

(B) if the prescription is transmitted orally, relayed to the dispensing pharmacist by the prescribing physician.

Sec. 5. Before requiring prior authorization for a single source

drug, the office shall seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board.

Sec. 6. (a) The office shall publish the decision to require prior authorization for a single source drug in a provider bulletin.

(b) IC 12-15-13-6 applies to a provider bulletin described in subsection (a).

Sec. 7. (a) Subject to subsection (b), the office may place limits on quantities dispensed or the frequency of refills for any covered drug for the purpose of:

(1) preventing fraud, abuse, waste, overutilization, or inappropriate utilization; or

(2) implementing a disease management program.

(b) Before implementing a limit described in subsection (a), the office shall:

(1) consider quality of care and the best interests of Medicaid recipients;

(2) seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board; and

(3) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

SECTION 14. IC 12-17.6-4-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 2.5. Prescription drugs provided under the program are subject to the requirements of IC 12-15-35.5.**

SECTION 15. IC 12-17.6-4-8, AS ADDED BY P.L.291-2001, SECTION 158, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8. **(a)** The office shall require the use of generic drugs in the program.

(b) The office shall use the preferred drug list implemented under IC 12-15-35-28.7.

SECTION 16. IC 25-1-9-6.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 6.8. (a) This section applies to a practitioner who is:**

(1) licensed to practice medicine or osteopathic medicine under IC 25-22.5; or

(2) licensed as an advanced practice nurse under IC 25-23.

(b) Before prescribing a psychotropic medication for a child for the treatment of attention deficit hyperactivity disorder, a practitioner described in subsection (a) shall:

(1) follow the most recent guidelines adopted by the American Academy of Pediatrics for the diagnosis and evaluation of a child with attention deficit hyperactivity disorder; and

(2) obtain, if the child:

(A) is a recipient of Medicaid under IC 12-15 or the children's health insurance program under IC 12-17.6, prior authorization; or

(B) is not described in clause (A), an opinion from another practitioner who is licensed under IC 25-22.5 that treatment with a psychotropic medication is appropriate for the child.

(c) In addition to the actions listed under section 4 of this chapter that subject a practitioner to the exercise of disciplinary sanctions, a practitioner described in subsection (a) is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board regulating the practitioner's profession finds that the practitioner has violated subsection (b).

SECTION 17. [EFFECTIVE UPON PASSAGE] **The chairperson shall make the appointments required under IC 12-15-35-20.5, as added by this act, not more than thirty (30) days after the effective date of this act.**

SECTION 18. [EFFECTIVE UPON PASSAGE] **Upon the effective date of this act, any drug that is included on the preferred drug list implemented by the drug utilization review board under IC 12-15-35-28, as amended by this act, may not require prior authorization.**

SECTION 19. [EFFECTIVE UPON PASSAGE] **(a) As used in this SECTION, "committee" refers to the therapeutics committee established by IC 12-15-35-20.5, as added by this act.**

(b) The initial terms of office for the members of the committee are as follows:

(1) Of the members appointed under IC 12-15-35-20.5(c)(1), as added by this act:

(A) two (2) members shall be appointed for a term of one (1) year;

(B) two (2) members shall be appointed for a term of two (2) years; and

(C) two (2) members shall be appointed for a term of three (3) years.

(2) Of the members appointed under IC 12-15-35-20.5(c)(2), as added by this act:

(A) one (1) member shall be appointed for a term of one (1)

year;

(B) two (2) members shall be appointed for a term of two (2) years; and

(C) two (2) members shall be appointed for a term of two (2) years.

(c) This SECTION expires December 31, 2003.

SECTION 20. **An emergency is declared for this act.**

SENATE MOTION

Mr. President: I move that Senator Simpson be added as second author of Senate Bill 228.

MILLER

COMMITTEE REPORT

Mr. President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 228, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 1, between lines 12 and 13, begin a new paragraph and insert:

"SECTION 3. IC 12-7-2-190.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 190.6. "Therapeutic classification" or "therapeutic category", for purposes of IC 12-15-35, has the meaning set forth in IC 12-15-35-17.5.**

SECTION 4. IC 12-15-35-17.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 17.5. As used in this chapter, "therapeutic classification" or "therapeutic category" means a group of pharmacologic agents primarily characterized by a significant similarity of the biochemical or physiological mechanism by which these agents result in the intended clinical outcome.**

SECTION 5. IC 12-15-35-20.1, AS ADDED BY P.L.231-1999, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 20.1. (a) Each board member **and each therapeutics committee member** shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board **or committee** for recommendation or other action.

(b) A board member **or therapeutics committee member** may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member **or therapeutics committee member** who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

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(b) The chairperson of the board elected under section 25 of this chapter shall, with the approval of a majority of a quorum of the board, appoint the members of the therapeutics committee.

(c) The therapeutics committee is composed of the following members:

(1) Six (6) physicians licensed under IC 25-22.5, including:

(A) one (1) physician with expertise in the area of infectious diseases;

(B) one (1) physician with expertise in the area of pediatrics;

(C) one (1) physician with expertise in the area of geriatrics;

(D) one (1) physician with expertise in psychiatric medicine;

(E) one (1) physician with expertise in the area of internal medicine and who specializes in the treatment of diabetes; and

(F) one (1) physician with expertise in the area of cardiovascular medicine.

(2) Five (5) pharmacists licensed under IC 25-26, including:

(A) one (1) pharmacist who has experience in pharmacy benefit management and is employed by a health maintenance organization that has a pharmacy benefit;

(B) one (1) pharmacist who is employed or has been employed by a hospital pharmacy or a retail pharmacy;

(C) one (1) pharmacist who is employed or has been employed in the area of long term care pharmacy;

(D) two (2) pharmacists who have a doctor of pharmacy degree or an equivalent degree and who have either:

(i) completed a residency in drug information; or

(ii) had at least three (3) years of recent experience in prescription drug formulary management, including therapeutic category review.

(d) Not more than three (3) of the individuals appointed by the chairperson under subsection (b) to the therapeutics committee may also be members of the board.

(e) At least three (3) of the members described in subsection (c)(1) and appointed under subsection (b) must have at least three (3) years of recent experience in prescription drug formulary management, including therapeutic category review.

(f) A member of the therapeutics committee may not:

(1) be employed by; or

(2) contract with;

a pharmaceutical manufacturer or labeler.

(g) The term of a member of the therapeutics committee is three

(3) years. A member may be reappointed to the committee upon the completion of the member's term.

(h) The expenses of the therapeutics committee shall be paid by the office.

(i) Each member of the therapeutics committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(j) Each member of the therapeutics committee who is a state employee is entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and any other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(k) The affirmative votes of a majority of the voting members appointed to the therapeutics committee are required for the committee to take action on any measure.

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SECTION 8. IC 12-15-35-28 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 28. **(a)** The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual

physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for Medicaid's fee for service program and primary care case management program in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The review of the committee's recommendations concerning a new prescription drug that has recently entered the market in order to determine whether the drug should be included on the preferred drug list.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give substantial consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program.

(d) A practitioner who is authorized to prescribe medication under IC 25 may prescribe a drug that is not on the preferred drug list if the practitioner receives prior authorization.

SECTION 9. IC 12-15-35-28.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 28.5. The therapeutics committee established under section 20.5 of this chapter shall do the following:**

(1) Advise and make recommendations to the board in the board's development and maintenance of a preferred drug list under section 28 of this chapter.

(2) Submit to the board a proposed preferred drug list that has been approved by a majority of the voting members of the therapeutics committee.

(3) Advise and make recommendations to the board in the board's annual review and maintenance of a preferred drug list.

SECTION 10. IC 12-15-35-28.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 28.7. (a) The board shall submit the approved preferred drug list to the office not later than August 1, 2002.**

(b) The office may implement the preferred drug list developed and approved by the board under section 28 of this chapter after June 30, 2002. However, the office shall implement this list not later than September 1, 2002.

(c) The office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(d) The office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(e) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.".

Page 5, between lines 16 and 17, begin a new paragraph and insert:

"SECTION 14. IC 25-1-9-6.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 6.8. (a) This section applies to a practitioner who is:**

(1) licensed to practice medicine or osteopathic medicine under IC 25-22.5;

(2) licensed as an advanced practice nurse under IC 25-23; or

(3) certified as a physician assistant under IC 25-27.5.

(b) Before prescribing a psychotropic medication for a child for the treatment of attention deficit hyperactivity disorder, a practitioner described in subsection (a) shall:

(1) follow the most recent guidelines adopted by the American Academy of Pediatrics for the diagnosis and evaluation of a child with attention deficit hyperactivity disorder; and

(2) obtain, if the child:

(A) is a recipient of Medicaid under IC 12-15 or the children's health insurance program under IC 12-17.6, prior authorization; or

(B) is not described in clause (A), an opinion from another practitioner who is licensed under IC 25-22.5 that treatment with a psychotropic medication is appropriate for the child.

(c) In addition to the actions listed under section 4 of this chapter that subject a practitioner to the exercise of disciplinary sanctions, a practitioner described in subsection (a) is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board regulating the practitioner's profession finds that the practitioner has violated subsection (b).

SECTION 15. [EFFECTIVE UPON PASSAGE] **The chairperson shall make the appointments required under IC 12-15-35-20.5, as added by this act, not more than thirty (30) days after the effective date of this act.**

SECTION 16. [EFFECTIVE UPON PASSAGE] **Upon the effective date of this act, any drug that is included on the preferred drug list implemented by the drug utilization review board under IC 12-15-35-28, as amended by this act, may not require prior authorization.**

SECTION 17. [EFFECTIVE UPON PASSAGE] **(a) As used in this SECTION, "committee" refers to the therapeutics committee established by IC 12-15-35-20.5, as added by this act.**

(b) The initial terms of office for the members of the committee are as follows:

(1) Of the members appointed under IC 12-15-35-20.5(c)(1), as added by this act:

(A) two (2) members shall be appointed for a term of one (1) year;

(B) two (2) members shall be appointed for a term of two (2) years; and

(C) two (2) members shall be appointed for a term of three (3) years.

(2) Of the members appointed under IC 12-15-35-20.5(c)(2), as added by this act:

(A) one (1) member shall be appointed for a term of one (1) year;

(B) two (2) members shall be appointed for a term of two (2) years; and

(C) two (2) members shall be appointed for a term of two (2) years.

(c) This SECTION expires December 31, 2003.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 228 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 10, Nays 0.

SENATE MOTION

Mr. President: I move that Senate Bill 228 be amended to read as follows:

Page 4, between lines 9 and 10, begin a new paragraph and insert:

"**(l) The therapeutics committee shall meet:**

(1) upon the call of the chairperson of the therapeutics committee; and

(2) at least quarterly.

(m) The chairperson and the vice chairperson of the therapeutics committee:

(1) each serve for a term of one (1) year; and

(2) must be elected from the therapeutics committee's membership at the therapeutics committee's first meeting each calendar year.

(n) A meeting held by the therapeutics committee must be open to the public in accordance with IC 5-14-1.5.".

Page 5, line 38, delete "for Medicaid's fee for service program and primary" and insert "**for:**

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the children's health insurance program under IC 12-17.6;".

Page 5, line 39, delete "care case management program".

Page 5, line 39, before "in" begin a new line block indented.

Page 6, between lines 22 and 23, begin a new paragraph and insert:

"**(e) The board, in consultation with the therapeutics committee, shall approve or deny the inclusion on the preferred drug list of a single source drug that is newly approved by the federal Food and Drug Administration on the earlier of:**

(1) thirty (30) days after the single source drug is approved by the federal Food and Drug Administration; or

(2) the date of the board's first scheduled meeting following the approval of the single source drug by the federal Food and Drug Administration.".

Page 8, between lines 30 and 31, begin a new paragraph and insert:

"SECTION 12. IC 12-15-35-43 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 43. **(a)** Confidential data or information obtained by pharmacists as part of prospective DUR are confidential but may be released to prescribers or others according to procedures established by the board.

(b) The board, the therapeutics committee, or the office may not

release proprietary information obtained as part of the development, implementation, or maintenance of a preferred drug list under this chapter.".

Page 10, between lines 32 and 33, begin a new paragraph and insert:

"SECTION 15. IC 12-17.6-4-8, AS ADDED BY P.L.291-2001, SECTION 158, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8. **(a)** The office shall require the use of generic drugs in the program.

(b) The office shall use the preferred drug list implemented under IC 12-15-35-28.7.".

Page 10, line 37, after ";" insert "**or**".

Page 10, line 38, delete "; or" and insert "**.**".

Page 10, delete line 39.

Renumber all SECTIONS consecutively.

(Reference is to SB 228 as printed January 30, 2002.)

MILLER

SENATE MOTION

Mr. President: I move that Senate Bill 228 be amended to read as follows:

Page 2, line 33, delete "Six (6)" and insert "**Seven (7)**".

Page 3, delete line 2.

Page 3, line 4, delete "medicine." and insert "**medicine; and**".

Page 3, between lines 4 and 5, begin a new line double block indented and insert:

"**(G) one (1) physician with expertise in the area of oncology or pain management.**".

Page 3, line 5, delete "Five (5)" and insert "**Six (6)**".

Page 3, line 10, delete "pharmacy or a retail".

Page 3, between lines 10 and 11, begin a new line double block indented and insert:

"**(C) one (1) pharmacist who is employed or has been employed by a retail pharmacy;**".

Page 3, line 11, delete "(C)" and insert "**(D)**".

Page 3, line 12, after "pharmacy;" insert "**and**".

Page 3, line 13, delete "(D)" and insert "**(E)**".

(Reference is to SB 228 as printed January 30, 2002.)

RIEGSECKER